UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,333	07/26/2001	Franco Pamparana	101615-00012	5701

7590 03/08/2004

ARENT FOX KINTNER PLOTKIN & KAHN PLLC
1050 CONNECTICUT AVENUE, N.W.
SUITE 400
WASHINGTON, DC 20036-5339

EXAMINER	
HENLEY III, RAYMOND J	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 03/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/869,333	PAMPARANA, FRANCO	
	Examiner	Art Unit	
	Raymond J. Henley III	1614	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-14,16-20,22-25,27 and 28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-14,16-20,22-25,27 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

CLAIMS 12-14, 16-20, 22-25, 27 AND 28 ARE PRESENTED FOR EXAMINATION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's "Preliminary"Amendment and Response filed on February 5, 2004 has been entered. Accordingly, the specification at page 1, after the title, and claims 12, 18, 24 and 27 have been amended and claims 15, 21, 26 and 29 have been canceled.

In light of the above amendments and Applicant's remarks at pages 6 and 7 of the response, the rejections under 35 U.S.C. 112, first paragraph and 35 U.S.C. 103 set forth in the previous Office action dated August 5, 2003 are withdrawn.

Claim Rejection - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18-20, 22 and 23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for preventing mortality or sudden death caused by the reoccurrence of a myocardial infarction (present specification at page 2, lines 11-15) in patients

who have suffered a myocardial infarction, does not reasonably provide enablement for preventing mortality or sudden death in general in patients who have suffered a myocardial infarction. Such would encompass death and/or mortality events that may or may not be preventable, e.g., due to Alzheimer's disease or otherwise to natural causes other than a reoccurrence of a myocardial infarction. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors as applied to the present application (see below are weighed, it is the examiner's position that the present specification would only enable the skilled artisan to prevent mortality or sudden death caused by the reoccurrence of a myocardial infarction (present specification at page 2, lines 1-15) in patients who have suffered a myocardial infarction.

(1) The nature of the invention.

The claims set forth methods for the prevention or mortality or sudden death in patients who have survived myocardial infarction in which essential fatty acids are administered.

(2) The state of the prior art.

The prior art recognizes that essential fatty acids of the type claimed can be employed for the prevention of sudden death or mortality caused by reoccurrence of a myocardial infarction in patients who have suffered myocardial infarction. See Leaf et al. (U.S. Patent No. 5,760,081) (the entire document is believed to be relevant).

(3) The relative skill of those in the art.

The relative skill of those in the art is high.

(4) The predictability or unpredictability of the art.

The unpredictability of the pharmaceutical chemistry/medical art is very high. As an example of the unpredictability in the art, the Examiner points to two very well known therapeutic agents, namely quinine and quinidine. Quinine and quinidine differ from each other only in that they are mirror images of each other. However, the therapeutic activity of each is quite distinct. Namely, quinine is effective for reducing a fever or as an anesthetic, while quinidine finds application as a cardiac suppressant. Also, respecting the objective of preventing mortality or sudden death in general in any patient population, the Examiner can find no reference which would support a contention that objective was known or expected by the skilled artisan using any therapeutic means.

(5) The breadth of the claims.

The claims are not limited to mortality or sudden death caused by the reoccurrence of a myocardial infarction in a patient who had previously suffered a myocardial infarction, but rather recite "mortality" and "sudden death" in general.

(6) The amount of direction or guidance presented.

The specification provides specific and adequate directions for preventing mortality or

sudden death caused by the reoccurrence of a myocardial infarction (present specification at page 2, lines 11-15) in patients who have suffered a myocardial infarction.

(7) The presence or absence of working examples.

Applicant at page 6 of the present specification merely shows compositions useful for preventing mortality or sudden death caused by the reoccurrence of a myocardial infarction in patients who have suffered a myocardial infarction. No data is supplied showing clinical data resulting from the administration of such compositions for preventing mortality or sudden death caused by anything other than the reoccurrence of a myocardial infarction in patients who have suffered a myocardial infarction.

(8) The quantity of experimentation necessary.

Because of the unpredictability of the art, see (4) above, it is believed that undue experimentation would be necessary to practice the invention of the scope claimed.

Accordingly, for the above reasons, claims 18-20, 22 and 23 are properly rejected under 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12-14, 16-20, 22-25, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Breivik et al. (U.S. Patent No. 5,502,077, cited by the Examiner) in light of Garrison et al. (The Nutrition Desk Reference, cited by the Examiner).

Breivik et al. teach fatty acid compositions containing at least 80% by weight of omega-3-fatty acids, salts or derivatives thereof, wherein eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) comprises at least 75% by weight of the total fatty acids. The compositions can be used for the treatment or prophylaxis of multiple risk factors for cardiovascular diseases. See the abstract. Breivik et al. further teach that cardiovascular diseases leading to morbidity and premature mortality is related to several risk factors such as hypertension and hypercholesterolemia (col. 1, lines 14-20) and that their compositions have an advantageous effect on such risk factors, i.e., treatment or prophylaxis (col. 2, lines 50-58).

The compositions of Breivik et al. may contain EPA and DHA in relative amounts of 1:2 to 2:1 (col. 2, line 53) and the EPA and DHA may be present in the form of an ester (col. 12, lines 31-34 and 40-44). Breivik et al. further teach that generally, for the average adult person the doses may vary from 1.0 to 10 grams depending on body size and the seriousness of the condition to be treated.

The Examiner wishes to note that in present claims 17 and 23, an EPA/DHA ratio of 0.9/1.5 is set forth. This ratio simplifies to 0.6/1. The ratios of the reference, i.e., 1:2 to 2:1, simplify to 0.5/1 to 2/1.

The difference between the above and the claimed subject matter lies in that Breivik et al. does not highlight the prevention of mortality caused by reoccurrence of cardiovascular events in a patient who has survived a myocardial infarction.

However, the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains

because Breivik et al. do teach the prevention of risk factors leading to a cardiovascular disease which causes premature mortality and thus the prevention of a cardiovascular disease which causes premature mortality. The selection of any specific patient population in whom to practice such prevention, including the myocardial infarction survivors of the present claims, would have been a matter well within the purview of the skilled artisan. The skilled artisan would have been motivated to select a patient such a myocardial infarction survivor because, as shown in the Table on page 150, col. 1, Garrison et al. show myocardial infarction, i.e., "Heart attack" to be a cardiovascular disease which would be encompassed by Breivik and the skilled artisan would have wanted to prevent the reoccurrence of such a disease, especially in a patient who had already suffered from a myocardial infarction.

Accordingly, for the above reasons, the claims are deemed to be properly rejected and none are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ray Henley whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 571-272-0584. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Raymond J. Henley III
Primary Examiner
Art Unit 1614

Mar. 1, 2004